

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS**

**IN RE: TESTOSTERONE REPLACEMENT  
THERAPY PRODUCTS LIABILITY  
LITIGATION**

**Case No. 1:14-CV-01748  
MDL 2545**

**JUDGE MATTHEW F. KENNELLY**

**THIS DOCUMENT APPLIES TO ALL CASES**

**MASTER ANSWER OF DEFENDANTS ABBVIE INC., ABBOTT LABORATORIES,  
ABBVIE PRODUCTS LLC AND UNIMED PHARMACEUTICALS, LLC TO  
PLAINTIFFS' MASTER LONG-FORM COMPLAINT AND JURY DEMAND**

Defendants AbbVie Inc., Abbott Laboratories,<sup>1</sup> AbbVie Products LLC, and Unimed Pharmaceuticals LLC (collectively “AbbVie”), by and through their attorneys, hereby provides this Master Answer to Plaintiffs’ Master Long-Form Complaint, and states as follows:

**ANSWER TO ALLEGATIONS REGARDING THE  
NATURE OF THIS MASTER COMPLAINT**

1. AbbVie admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in Case Management Order (CMO) 20 entered in the pending MDL relating to testosterone replacement therapy products (“TRTs”). The Master Complaint, being in writing, speaks for itself and any remaining or inconsistent allegations are denied. AbbVie further denies that Plaintiffs alleged injuries are the result of any wrongful conduct by AbbVie and that Plaintiffs are entitled to relief on any of the within claims or causes of action.

2. AbbVie admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in CMO 20 entered in the pending MDL relating to TRTs, and that individual plaintiffs are expected to utilize short form complaints consistent with Exhibit A and CMO 20. Any remaining or inconsistent allegations are denied.

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<sup>1</sup> AbbVie was established at the beginning of 2013 as an independent, publicly traded company from the research-based pharmaceutical business of codefendant Abbott Laboratories which no longer sells AndroGel in the United States.

3. AbbVie admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in Case Management Order (CMO) 20 entered in the pending MDL relating to TRTs, and that individual plaintiffs are expected to utilize short form complaints consistent with Exhibit A and CMO 20. The Master Complaint, as well as any short form complaint, being in writing, speak for themselves and any remaining or inconsistent allegations are denied. AbbVie further denies that Plaintiffs' alleged injuries are the result of any wrongful conduct by AbbVie and that Plaintiffs are entitled to relief on any of the within claims or causes of action.

**ANSWER TO ALLEGATIONS REGARDING  
THE NATURE OF THIS ACTION**

4. AbbVie admits that Plaintiffs purport to seek compensation for personal injuries allegedly resulting from the use of various TRT products and that their claims, being in writing, speak for themselves. AbbVie denies that its TRT product, AndroGel, marketed in a 1% and 1.62% formulation, was defective or that it caused the injuries alleged and further denies that Plaintiffs are in any way entitled to damages or other relief. Any remaining or inconsistent allegations are denied.

5. AbbVie admits that AndroGel is approved for use as indicated by its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

6. AbbVie admits that its TRT product, AndroGel, marketed in a 1% and 1.62% formulation, is one of several TRT products at issue in the pending MDL and that the Master Complaint, being in writing, speaks for itself. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

7. AbbVie admits that it engaged in promotional activities related to AndroGel and that, at various times, it also supported disease state awareness related to men's health issues, including hypogonadism, referred to as low testosterone or Low T. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

8. AbbVie admits that Androgen Deficiency in Adult Males ("ADAM") refers to a set of questions regarding the signs and symptoms of hypogonadism and that the ADAM questionnaire, being in writing, speaks for itself. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

9. Denied.

10. Denied.

11. Denied.

**ANSWER TO ALLEGATIONS REGARDING  
JURISDICTION AND VENUE**

12. The allegations in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, upon reasonable investigation, AbbVie admits that diversity jurisdiction exists as to most of the claims brought by Plaintiffs in this MDL, generally, but reserves the right to challenge such jurisdiction in a particular case should further factual investigation reveal otherwise.

13. The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, AbbVie admits that, upon information and belief, Plaintiffs are seeking in excess of seventy-five thousand dollars (\$75,000) in each individual case but denies that Plaintiffs are entitled to any recovery.

## **ANSWER TO ALLEGATIONS REGARDING PARTIES**

### **Answer to Allegations Regarding Plaintiffs**

14. AbbVie admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in Case Management Order (CMO) 20 entered in the pending MDL relating to TRTs. The Master Complaint, being in writing, speaks for itself. AbbVie denies that Plaintiffs' alleged injuries are the result of any wrongful conduct by AbbVie and further denies that Plaintiffs are entitled to relief on any of the within claims or causes of action.

15. Denied.

16. The allegations in Paragraph 16 state legal conclusions to which no response is required. To the extent a response is required, the averments of Paragraph 16 are denied.

### **Answer to Allegations Regarding Defendants**

#### *Answer to Allegations Regarding the AbbVie Defendants*

17. Admitted.

18. Admitted.

19. Admitted.

20. Admitted.

21. Admitted.

22. Admitted.

23. Admitted.

24. In response to Paragraph 24 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

25. In response to Paragraph 25 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

26. In response to Paragraph 26 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

27. In response to Paragraph 27 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

28. It is admitted that Plaintiffs refer in their Complaint to AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, Unimed Pharmaceuticals LLC, Solvay, S.A., Besins Healthcare Inc., and Besins Healthcare, S.A. collectively as “AbbVie.” It is denied that such characterization is reasonable, accurate or appropriate and also denied that Solvay, S.A., Besins Healthcare, S.A., and Besins Healthcare Inc. may be “defined” as part of “AbbVie.” AbbVie does not file this Master Answer on behalf of Solvay, S.A., Besins Healthcare, S.A. and/or Besins Healthcare Inc.

29. It is admitted that Plaintiffs’ claims against AbbVie purportedly relate to AndroGel 1% and 1.62%. AbbVie denies that such claims have merit and further denies that Plaintiffs are entitled to relief on any of the within claims or causes of action. Any remaining or inconsistent allegations are denied.

*Answer to Allegations Regarding the Lilly Defendants*

30. - 38. In response to Paragraphs 30-38 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations Regarding the Endo, Auxilium, and GSK*

39. - 44. In response to Paragraph 39-44 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations Regarding the Pfizer Defendants*

45. - 48. In response to Paragraph 45-48 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations Regarding the Actavis Defendants*

49. - 56. In response to Paragraph 49-56 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

**ANSWER TO ALLEGATIONS OF FACTS  
COMMON TO ALL CLAIMS**

**Answer to Allegations Regarding the TRT Products**

57. It is admitted that TRT products replace the androgen hormone testosterone, which is normally produced by men's bodies, there are various available methods of delivering this replacement hormone, and some, but not all, of these methods are identified in Paragraph 57. Any remaining or inconsistent allegations are denied.

58. It is admitted that AndroGel is delivered transdermally, it is applied to the skin in the form of a gel, and AndroGel is available in both a 1% and a 1.62% formulation. AbbVie further admits that Unimed Pharmaceuticals Inc. submitted a New Drug Application to the FDA for AndroGel 1% on or about April 28, 1999 and that Solvay Pharmaceuticals Inc. acquired Unimed prior to FDA approval of AndroGel 1% in 2000. AbbVie otherwise denies that Plaintiffs have accurately characterized the corporate relationships and transactions set forth in Paragraph 58. Any remaining or inconsistent allegations are denied.

59. It is admitted that AbbVie or its predecessors have, at various times, engaged in developing, researching, labeling, marketing, promoting and/or selling AndroGel 1% and/or 1.62%. Any remaining or inconsistent allegations are denied.

60. - 75. In response to Paragraph 60-75 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

76. It is admitted that AndroGel delivers testosterone and that testosterone is the primary hormone responsible for normal male growth and development of male sex organs and secondary sex characteristics. It is further admitted that testosterone plays a role in many aspects of overall male health and well-being including but not limited to those identified in paragraph 76. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

77. It is admitted that the medical literature discusses the fact of some gradual, expected decline in testosterone levels in adult males over time. Any remaining or inconsistent allegations are denied.

78. It is admitted that some men suffer from medical conditions that impair their ability to make testosterone and that “primary hypogonadism” and “hypogonadotropic hypogonadism” refer to medical conditions which are associated with reduced or no production and levels of testosterone. Any remaining or inconsistent allegations are denied.

79. It is admitted that hypogonadism is a medical condition that is characterized by the nonproduction or underproduction of testosterone. It is further admitted that the medical community recognizes hypogonadism as an endocrine condition that may be appropriately treated, as well as the health benefits of normal testosterone levels. Any remaining or inconsistent allegations are denied.

80. It is admitted that AndroGel has been approved for use as a testosterone replacement therapy upon prescription of a learned intermediary and that the FDA approved

label for AndroGel, being in writing, speaks for itself. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

**Answer To Allegations Regarding Regulatory History and Approved Uses**

81. - 88. In response to Paragraph 81-88 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

89. The original approved AndroGel 1% product label, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

90. The original approved AndroGel 1.62% product label, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

91. The FDA approved AndroGel 1% and 1.62% product labels, being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

92. - 99. In response to Paragraph 92-99 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

100. The FDA approved AndroGel 1% and 1.62% product labels, being in writing, speak for themselves. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

101. Denied.

**Answer to Allegations Regarding Defendants' Marketing to Consumers and Physicians for Off-Label Use**

102. The allegations in Paragraph 102 state legal conclusions to which no response is required. To the extent a response is required, AbbVie denies that Paragraph 102 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.



103. The allegations in Paragraph 103 state legal conclusions to which no response is required. To the extent a response is required, AbbVie denies that Paragraph 103 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

104. The allegations in Paragraph 104 state legal conclusions to which no response is required. To the extent a response is required, AbbVie denies that Paragraph 104 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

105. The allegations in Paragraph 105 state legal conclusions to which no response is required. To the extent a response is required, AbbVie denies that Paragraph 105 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

106. The allegations in Paragraph 106 state legal conclusions to which no response is required. To the extent a response is required, AbbVie denies that Paragraph 106 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

107. The allegations in Paragraph 107 state legal conclusions to which no response is required. To the extent a response is required, it is admitted that the FDA approved AndroGel for use as a testosterone replacement therapy upon prescription of a learned intermediary, and that the FDA-approved labels for AndroGel 1% and 1.62%, being in writing, speak for themselves. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

108. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

109. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

110. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

111. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

112. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

113. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations of AbbVie's Off-Label Marketing*

114. It is admitted that AbbVie promoted AndroGel consistent with its knowledge and understanding of the FDA approved labels. Any remaining or inconsistent allegations are denied.

115. It is admitted that prior to the launch of AndroGel in 2000, Unimed submitted promotional materials to the FDA for review and received certain comments, which being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

116. To the extent Paragraph 116 purports to characterize unidentified written communications with the FDA, such communications, being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

117. To the extent Paragraph 117 purports to characterize unidentified written communications with the FDA, such communications, being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

118. It is admitted that the *Journal of the American Medical Association* published an article in August 2013 titled “Trends in Androgen Prescribing in the United States, 2001 to 2011.” The publication, being in writing, speaks for itself. AbbVie lacks knowledge or information sufficient to form a belief regarding the truth of any hearsay statements attributed to others and therefore denies them. Any remaining or inconsistent allegations are denied.

119. It is admitted that AbbVie, at times unspecified in Plaintiffs’ Master Complaint, utilized direct to consumer advertising through various media as well as disease state awareness materials, and supported the web-sites [www.IsItLowT.com](http://www.IsItLowT.com) and [www.DriveForFive.com](http://www.DriveForFive.com). Any remaining or inconsistent allegations are denied.

120. It is admitted that AbbVie, at times unspecified in Plaintiffs’ Master Complaint, utilized direct to consumer television to promote AndroGel and/or for the purpose of disease state awareness. Any remaining or inconsistent allegations are denied.

121. It is admitted that AbbVie, at times unspecified in Plaintiffs’ Master Complaint, supported the websites [www.IsItLowT.com](http://www.IsItLowT.com) and [www.DriveForFive.com](http://www.DriveForFive.com), which being in writing speak for themselves. Any remaining or inconsistent allegations are denied.

122. It is admitted that AbbVie supported the disease state awareness websites [www.IsItLowT.com](http://www.IsItLowT.com) and [www.DriveForFive.com](http://www.DriveForFive.com), which being in writing speak for themselves. Any remaining or inconsistent allegations are denied.

123. AbbVie admits that an article by Natasha Singer, titled “Selling that New-Man Feeling,” was published in the *New York Times* on or around November 23, 2013. AbbVie

further admits that, at times unspecified in Plaintiffs' Master Complaint, AbbVie utilized the Androgen Deficiency in Aging Men or ADAM questionnaire to facilitate discussions between patients and their doctors and that, being in writing, it speaks for itself. AbbVie lacks knowledge or information sufficient to form a belief regarding the truth of any hearsay statements attributed to others and therefore denies them. Any remaining or inconsistent allegations are denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. AbbVie lacks knowledge or information sufficient to form a belief regarding the unidentified "2004 memo" described but not identified or cited in full. As such, AbbVie denies the allegations of Paragraph 128.

129. It is admitted that IsItLowT.com and DriveForFive.com were disease state awareness websites maintained by AbbVie which, being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

130. AbbVie admits that an article by Shannon Pettypiece, titled *Are Testosterone Drugs the Next Viagra?* was published in *Bloomberg Business Week* on or around May 10, 2012. AbbVie lacks knowledge or information sufficient to form a belief regarding the truth of any hearsay statements attributed to others and therefore denies them. Any remaining or inconsistent allegations are denied.

131. AbbVie admits that there is an AndroGel-related program called "The Restoration Program" which provides AndroGel patients with information, including regarding co-pay assistance, and that paragraph 131 appears to contain a selected screenshot from an AndroGel

website discussing The Restoration Program at a time unspecified in the Master Complaint. Any remaining or inconsistent allegations are denied.

132. AbbVie admits that an article by Larry Dobrow, titled "All-Star Large Pharma Marketing Team of the Year: AndroGel®," was published by Medical Marketing & Media in January 2, 2013, which being in writing speaks for itself. AbbVie lacks knowledge or information sufficient to form a belief regarding the truth of any hearsay statements or opinions attributed to others, and therefore denies them. AbbVie denies any remaining or inconsistent allegations.

133. Denied.

134. Denied.

135. AbbVie admits that it has, at various times, engaged in marketing and promoting of AndroGel to healthcare providers. Any remaining or inconsistent allegations are denied.

136. AbbVie admits that it has, at various times, engaged in marketing and promoting of AndroGel to healthcare providers, and has provided patient-directed materials. Any remaining or inconsistent allegations are denied.

137. Denied.

138. Denied.

139. AbbVie admits that it is aware of applicable regulations regarding the promotion of prescription pharmaceuticals. Because the manner in which Plaintiffs are using the terms "off-label" and "label-expansion" is not clear from the face of the Master Complaint, AbbVie denies any characterization suggested by Plaintiffs. Any remaining or inconsistent allegations are denied.

140. AbbVie admits that it is aware of applicable regulations regarding the promotion of prescription pharmaceuticals. Because the manner in which Plaintiffs are using the terms “off-label” and “label-expansion” is not clear from the face of the Master Complaint, AbbVie denies any characterization suggested by Plaintiffs. Any remaining or inconsistent allegations are denied.

141. Denied.

*Answer to Allegations of Lilly’s Off-Label Marketing*

142.- 206. In response to Paragraph 142-206 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations of Endo’s Off-Label Marketing*

207.- 256. In response to Paragraph 207-256 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations of Auxilium’s and GSK’s Off-Label Marketing*

257.- 350. In response to Paragraph 257-350 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer to Allegations of Pfizer’s Off-Label Marketing*

351.- 372. In response to Paragraph 351-372 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

*Answer Regarding Allegations of Actavis’s Off-Label Marketing*

373.- 385. In response to Paragraph 373-385 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

**Answer Regarding Allegations of Defendants' Failure  
to Warn of the Risks and Dangers of TRT Products**

386. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

387. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

388. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

389. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

390. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

391. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

392. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

393. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

394. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

395. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

396. It is admitted that the medication guide instructed patients to inform their healthcare provider if they had certain conditions and that such materials, being in writing, speak

for themselves. Any remaining or inconsistent allegations are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

397. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

398. It is admitted that the AndroGel product labels and medication guides provided appropriate information regarding potential increases in red blood cell count and that such materials, being in writing, speak for themselves. It is denied that the label should have contained or in any way failed to contain the remaining warnings set forth in Paragraph 398 or that Plaintiffs' proffered warnings are accurate or appropriate. Any remaining or inconsistent allegations are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

399. It is admitted that the AndroGel product labels and medication guides provided appropriate information regarding monitoring of potential increases in red blood cell count and that such materials, being in writing, speak for themselves. It is denied that the label should have contained or in any way failed to contain the remaining warnings or instructions set forth in Paragraph 399 or that Plaintiffs' proffered warnings and instructions are accurate or appropriate. Any remaining or inconsistent allegations are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

400. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

401. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.



402. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

403. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

404. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

405. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

406. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

407. Denied.

408. In response to Paragraph 408 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

409. In response to Paragraph 409 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

410. In response to Paragraph 410 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

411. In response to Paragraph 411 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

412. In response to Paragraph 412 of the Complaint, as the allegations are not directed to AbbVie, AbbVie makes no response.

413. Admitted.

414. Denied that Paragraph 414 accurately or completely describes the conclusions of the “Vigen Paper” or that such study reached any reliable or accurate conclusions.

415. Admitted.

416. Denied.

417. Denied.

418. It is admitted that on or about June 19, 2014, the FDA issued an announcement regarding the modification of certain approved warning language. The FDA’s announcement, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

419. It is admitted that AbbVie, in cooperation with the FDA, modified the product label and medication guide on or about June 19, 2014 and that such modification, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

420. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

421. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

422. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

423. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

424. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

425. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

426. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

427. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

428. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

429. It is admitted that on March 3, 2015 the FDA issued an FDA Drug Safety Communication, which being in writing speaks for itself. AbbVie denies any remaining or inconsistent allegations. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

**Answer to Allegations of Defendants' Fraud on the FDA**

430. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

431. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

432. The allegations in Paragraph 432 state legal conclusions to which no response is required. To the extent a response is required, it is denied that Plaintiffs have completely or accurately set forth the entirety of 21 U.S.C. § 331 or fairly conveyed its meaning. Any remaining or inconsistent allegations are denied.

433. The allegations in Paragraph 433 state legal conclusions to which no response is required. To the extent a response is required, it is denied that Plaintiffs have completely or

accurately set forth the entirety of 21 U.S.C. § 352 or fairly conveyed its meaning. Any remaining or inconsistent allegations are denied.

434. The allegations in Paragraph 434 state legal conclusions to which no response is required. To the extent a response is required, it is admitted only that Plaintiffs have accurately transcribed 21 U.S.C. § 321(n). Any remaining or inconsistent allegations are denied.

435. It is admitted that the FDA approved AndroGel 1% and later AndroGel 1.62%. The approved labeling for both AndroGel 1% and AndroGel 1.62%, being in writing, speaks for themselves. Any remaining or inconsistent allegations are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

436. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

437. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

438. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

439. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

440. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

441. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

442. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

443. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

444. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

445. It is admitted that the quoted language is part of a letter to the editor that appeared in the New England Journal of Medicine in 2004 attributed to Dr. Daniel Shames, Food and Drug Administration. AbbVie denies that this letter represents the view of FDA and otherwise denies any remaining or inconsistent allegations.

446. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 446 and they are, therefore, denied.

447. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 447 and they are, therefore, denied.

448. Denied.

449. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

450. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

451. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

452. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

453. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

454. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

455. AbbVie admits that Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. are identified as authoring an “Invited Commentary” in or around August 26, 2013, titled *Low T as a Template: How to Sell Disease*, in *JAMA* which, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

456. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

457. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

458. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

459. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

460. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

461. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

462. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

463. It is admitted that a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee (“Ad.

Comm.”) was convened on September 17, 2014 and that the agenda, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

464. It is admitted that the Ad. Comm. published Summary Minutes on October 5, 2014. The Summary Minutes, being in writing, speak for themselves and any remaining or inconsistent allegations are denied.

465. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **Answer to Allegations of Fraudulent Concealment and Discovery Rule**

466. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

467. The allegations in Paragraph 467 state legal conclusions to which no response is required. To the extent a response is required, denied.

468. The allegations in Paragraph 468 state legal conclusions to which no response is required. To the extent a response is required, denied.

469. The allegations in Paragraph 469 state legal conclusions to which no response is required. To the extent a response is required, denied.

### **ANSWER TO CLAIMS FOR RELIEF**

#### **ANSWER TO FIRST CLAIM FOR RELIEF**

##### **Strict Liability – Design Defect**

470. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

471. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

472. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

473. The allegations in Paragraph 473 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

474. The allegations in Paragraph 474 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

475. The allegations in Paragraph 475 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

476. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 476 and they are, therefore, denied.

477. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

478. The allegations in Paragraph 478 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

479. The allegations in Paragraph 479 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.



**ANSWER TO SECOND CLAIM FOR RELIEF**

**Strict Liability – Failure to Warn**

480. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

481. The allegations in Paragraph 481 state legal conclusions to which no response is required. To the extent a response is required, it is denied that AbbVie engaged in all of the activities set forth in Paragraph 481 and it is further denied that AbbVie had any duty to warn of risks of AndroGel not described in its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

482. The allegations in Paragraph 482 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

483. The allegations in Paragraph 483 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

484. The allegations in Paragraph 484 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

485. The allegations in Paragraph 485 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

486. The allegations in Paragraph 486 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

487. The allegations in Paragraph 487 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

488. The allegations in Paragraph 488 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

489. The allegations in Paragraph 489 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO THIRD CLAIM FOR RELIEF**

##### **Negligence**

490. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

491. The allegations in Paragraph 491 state legal conclusions to which no response is required. To the extent a response is required, it is denied that AbbVie engaged in all of the activities set forth in Paragraph 491 and it is further denied that AbbVie had any duty to warn of risks of AndroGel not described in its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

492. The allegations in Paragraph 492 state legal conclusions to which no response is required. To the extent a response is required it is denied that AbbVie had any duty to warn of risks of AndroGel not described in its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

493. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

494. The allegations in Paragraph 494 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

495. The allegations in Paragraph 495 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

496. The allegations in Paragraph 496 state legal conclusions to which no response is required. To the extent a response is required it is denied that AbbVie had any duty to warn of risks of AndroGel or otherwise provide information not described in its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

497. The allegations in Paragraph 497 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

498. The allegations in Paragraph 498 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

499. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

500. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

501. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

502. The allegations in Paragraph 502 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

503. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

504. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

505. The allegations in Paragraph 505 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

506. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

507. The allegations in Paragraph 507 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

508. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

509. The allegations in Paragraph 509 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO FOURTH CLAIM FOR RELIEF**

##### **Negligent Misrepresentation**

510. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

511. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

512. The allegations in Paragraph 512 state legal conclusions to which no response is required. To the extent a response is required, it is denied that AbbVie had any duty to warn directly to Plaintiffs or other consumers or to provide prescribing physicians warning information not consistent with its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

513. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

514. The allegations in Paragraph 514 state legal conclusions to which no response is required. To the extent a response is required it is denied that AbbVie had any duty to warn directly to Plaintiffs or other consumers or to provide prescribing physicians warning information not consistent with its FDA-approved label. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

515. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

516. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

517. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

518. The allegations in Paragraph 518 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

519. The allegations in Paragraph 519 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

520. The allegations in Paragraph 520 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

521. The allegations in Paragraph 521 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

**ANSWER TO FIFTH CLAIM FOR RELIEF**

**Breach of Implied Warranty of Merchantability**

522. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

523. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

524. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

525. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

526. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

527. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 527 and they are, therefore, denied.

528. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

529. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

530. The allegations in Paragraph 530 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

531. The allegations in Paragraph 531 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

**ANSWER TO SIXTH CLAIM FOR RELIEF**

**Breach of Express Warranty**

532. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

533. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

534. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

535. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

536. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

537. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

538. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 538 and they are, therefore, denied.



539. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

540. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

541. The allegations in Paragraph 541 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

542. The allegations in Paragraph 542 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO SEVENTH CLAIM FOR RELIEF**

##### **Fraud**

543. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

544. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

545. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

546. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

547. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

548. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

549. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

550. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

551. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

552. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

553. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

554. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

555. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

556. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

557. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

558. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

559. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

560. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

561. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 561 and they are, therefore, denied.

562. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 562 and they are, therefore, denied.

563. The allegations in Paragraph 563 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

564. The allegations in Paragraph 564 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

565. The allegations in Paragraph 565 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO EIGHTH CLAIM FOR RELIEF**

##### **Redhibition**

566. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

567. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

568. It is admitted that AbbVie sold and promoted AndroGel. As to any allegations that are not directed to AbbVie, AbbVie makes no response. Any remaining or inconsistent allegations are denied.

569. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

570. The allegations in Paragraph 570 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

571. The allegations in Paragraph 571 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO NINTH CLAIM FOR RELIEF**

##### **Consumer Protection**

572. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

573. The allegations in Paragraph 573 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

574. The allegations in Paragraph 574 state legal conclusions to which no response is required.

575. The allegations in Paragraph 575 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

576. The allegations in Paragraph 576 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

577. The allegations in Paragraph 577 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

578. The allegations in Paragraph 578 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

579. The allegations in Paragraph 579 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

580. The allegations in Paragraph 580 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

581. The allegations in Paragraph 581 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

582. The allegations in Paragraph 582 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

583. The allegations in Paragraph 583 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

584. The allegations in Paragraph 584 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

585. The allegations in Paragraph 585 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

586. The allegations in Paragraph 586 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

587. The allegations in Paragraph 587 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

588. The allegations in Paragraph 588 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

589. The allegations in Paragraph 589 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

590. The allegations in Paragraph 590 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

591. The allegations in Paragraph 591 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

592. The allegations in Paragraph 592 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

593. The allegations in Paragraph 593 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

594. The allegations in Paragraph 594 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

595. The allegations in Paragraph 595 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

596. The allegations in Paragraph 596 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

597. The allegations in Paragraph 597 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

598. The allegations in Paragraph 598 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

599. The allegations in Paragraph 599 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

600. The allegations in Paragraph 600 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

601. The allegations in Paragraph 601 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

602. The allegations in Paragraph 602 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

603. The allegations in Paragraph 603 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.



604. The allegations in Paragraph 604 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

605. The allegations in Paragraph 605 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

606. The allegations in Paragraph 606 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

607. The allegations in Paragraph 607 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

608. The allegations in Paragraph 608 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

609. The allegations in Paragraph 609 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

610. The allegations in Paragraph 610 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

611. The allegations in Paragraph 611 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

612. The allegations in Paragraph 612 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

613. The allegations in Paragraph 613 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

614. The allegations in Paragraph 614 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

615. The allegations in Paragraph 615 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

616. The allegations in Paragraph 616 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

617. The allegations in Paragraph 617 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

618. The allegations in Paragraph 618 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

619. The allegations in Paragraph 619 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

620. The allegations in Paragraph 620 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

621. The allegations in Paragraph 621 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

622. The allegations in Paragraph 622 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

623. The allegations in Paragraph 623 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

624. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

625. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

626. The allegations in Paragraph 626 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

627. The allegations in Paragraph 627 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO TENTH CLAIM FOR RELIEF**

##### **Unjust Enrichment**

628. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

629. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

630. AbbVie lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 630 and they are, therefore, denied.

631. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

632. The allegations in Paragraph 632 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO ELEVENTH CLAIM FOR RELIEF**

##### **Wrongful Death**

633. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

634. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

635. The allegations in Paragraph 635 state legal conclusions to which no response is required. To the extent the averments of Paragraph 635 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

636. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

637. The allegations in Paragraph 637 state legal conclusions to which no response is required. To the extent the averments of Paragraph 637 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

638. The allegations in Paragraph 638 state legal conclusions to which no response is required. To the extent the averments of Paragraph 638 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

639. The allegations in Paragraph 639 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO TWELFTH CLAIM FOR RELIEF**

##### **Survival Action**

640. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

641. The allegations in Paragraph 641 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

642. The allegations in Paragraph 642 state legal conclusions to which no response is required. To the extent the averments of Paragraph 642 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

643. The allegations in Paragraph 643 state legal conclusions to which no response is required. To the extent the averments of Paragraph 643 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

644. The allegations in Paragraph 644 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

### **THIRTEENTH CLAIM FOR RELIEF**

#### **Loss of Consortium**

645. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

646. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

647. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

648. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

649. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

650. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

651. The allegations in Paragraph 651 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

652. The allegations in Paragraph 652 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

#### **ANSWER TO FOURTEENTH CLAIM FOR RELIEF**

##### **Punitive Damages**

653. AbbVie incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

654. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

655. Denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

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657. The allegations in Paragraph 657 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to AbbVie, AbbVie makes no response.

### **RESPONSE TO “PRAYER FOR RELIEF”**

Responding to the unnumbered WHEREFORE paragraph following Paragraph 657 of the Complaint, including each subpart, AbbVie denies that its conduct or AndroGel caused or contributed to Plaintiffs’ injuries and denies that it is liable to Plaintiffs for damages or any other relief sought in the Complaint.

### **AFFIRMATIVE DEFENSES**

AbbVie asserts the following affirmative defenses, which shall apply to this Master Complaint as well as any individual complaint that is or should, at any time, become part of this MDL. By asserting these affirmative defenses, AbbVie does not allege or admit that it has the burden of proof or the burden of persuasion with respect to any of these matters.

#### **FIRST DEFENSE**

658. Plaintiffs’ Master Complaint fails to state a claim upon which relief may be granted.

#### **SECOND DEFENSE**

659. To the extent one or more of the claimants covered by this Master Complaint filed and/or had their action removed to any improper or inconvenient forum, such complaint should be dismissed and/or transferred for lack of venue and/or on the grounds of *forum non conveniens*.



### **THIRD DEFENSE**

660. Plaintiffs' claims may be barred by the doctrine(s) contained in Restatement (Second) of Torts § 402A, and comments thereto, including but not limited to comments j and k, and/or Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

### **FOURTH DEFENSE**

661. Plaintiffs' claims may be barred because the risks alleged to be associated with the use of AndroGel were outweighed by the medication's utility.

### **FIFTH DEFENSE**

662. Plaintiffs' claims may be barred, in whole or in part, by misuse or unintended use of AndroGel.

### **SIXTH DEFENSE**

663. Plaintiffs' claims may be barred, in whole or in part, by the learned intermediary or informed intermediary doctrine.

### **SEVENTH DEFENSE**

664. Plaintiffs' claims may be barred because Plaintiffs' injuries, if any, were caused, in whole or in part, by the intervening or superseding conduct of Plaintiffs, independent third parties, or events that were extraordinary under the circumstances, not foreseeable in the normal course, or independent of or far removed from AbbVie's conduct or control.

### **EIGHTH DEFENSE**

665. Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs provided learned or informed consent to the use of AndroGel.

**NINTH DEFENSE**

666. Plaintiffs' claims may be barred, in whole or in part, by the doctrines of comparative fault or contributory negligence.

**TENTH DEFENSE**

667. Plaintiffs' claims may be barred, in whole or in part, by the negligent and/or otherwise wrongful conduct of others, constituting an intervening or superseding cause of the alleged harm

**ELEVENTH DEFENSE**

668. Plaintiffs' fraud-based claims may be barred for failure to plead them with the requisite particularity or specificity.

**TWELFTH DEFENSE**

669. Plaintiffs' fraud-based claims may be barred, in whole or in part, because Plaintiffs did not rely to their detriment upon any statement by AbbVie in determining to use AndroGel.

**THIRTEENTH DEFENSE**

670. Plaintiffs' claims may be barred, in whole or in part, by applicable statutes of limitations and/or repose.

**FOURTEENTH DEFENSE**

671. To the extent any Complaint asserts claims for breach of express or implied warranty, Plaintiffs lack the requisite privity with AbbVie to sustain such claims.

**FIFTEENTH DEFENSE**

672. To the extent any Complaint asserts claims for breach of express or implied warranty, such claims are barred because Plaintiffs did not reasonably rely on any alleged

express or implied warranty, and because Plaintiffs did not give AbbVie adequate notice of any alleged breach of warranty, express or implied.

#### **SIXTEENTH DEFENSE**

673. Plaintiffs' claims may be barred, in whole or in part, by the doctrines of waiver, laches, estoppel, release, or statutory and regulatory compliance.

#### **SEVENTEENTH DEFENSE**

674. Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid by any insurance or other health benefits plan.

#### **EIGHTEENTH DEFENSE**

675. Plaintiffs' claims may be barred, in whole or in part, by the doctrine of assumption of risk.

#### **NINETEENTH DEFENSE**

676. Plaintiffs' claims are barred because AndroGel was designed, manufactured and marketed in accordance with the state of the art and when AndroGel left the control of AbbVie no practical and technically feasible alternative formulation was available that would have prevented the harm for which Plaintiffs seek to recover without substantially impairing the safety, efficacy, or usefulness of the products for their intended use.

#### **TWENTIETH DEFENSE**

677. Plaintiffs' damages, if any, may be limited, in whole or in part, by Plaintiffs' failure to mitigate.

#### **TWENTY-FIRST DEFENSE**

678. Plaintiffs' claims are barred, in whole or in part, because AndroGel is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with determinations by the FDA specifying the language that should be used in the labeling accompanying AndroGel. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

#### **TWENTY-SECOND DEFENSE**

679. Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of AbbVie and its activities with respect to AndroGel, have been and are conducted under the supervision of the FDA.

#### **TWENTY-THIRD DEFENSE**

680. To the extent that Plaintiffs seek punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### **TWENTY-FOURTH DEFENSE**

681. Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.

#### **TWENTY-FIFTH DEFENSE**

682. AbbVie is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any applicable law or rule of law or governing statute of any state, including but not limited to any relevant product liability acts and/or consumer fraud and/or unfair competition acts, that would bar or otherwise limit any of the claims asserted by Plaintiffs.

#### **TWENTY-SIXTH DEFENSE**

683. To the extent Plaintiffs seek recovery of punitive or exemplary damages against AbbVie, any such damages are barred and/or limited by applicable laws and/or standards of proof.

#### **TWENTY-SEVENTH DEFENSE**

684. To the extent Plaintiffs seek recovery of punitive, exemplary or aggravated damages against AbbVie, any such damages claims are in violation of and are barred by the Constitution of the United States and any relevant comparable state constitutional provisions, including but not limited to, the Due-Process and Equal Protection Clauses contained in the Fifth and Fourteenth Amendments; the Excessive Fines Clause of the Eighth Amendment; and the Tenth Amendment.

#### **TWENTY-EIGHTH DEFENSE**

685. To the extent that Plaintiffs seek punitive, exemplary, or aggravated damages, AbbVie specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and cases subsequent to *BMW*, including *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007).

**TWENTY-NINTH DEFENSE**

686. Plaintiffs' claims may be barred because of Plaintiffs' failure to join necessary and indispensable parties.

**THIRTIETH DEFENSE**

687. To the extent Plaintiffs' claims related to AbbVie's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitutions of any applicable state, such claims are barred.

**THIRTY-FIRST DEFENSE**

688. To the extent Plaintiffs assert claims that depend solely on violations of federal law, including claims of a "fraud on the FDA" with respect to AbbVie's disclosure of information related to the safety of AndroGel, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

**THIRTY-SECOND DEFENSE**

689. To the extent applicable, AbbVie asserts and preserves all claims for indemnification and/or contribution from any person and/or entity whose negligence or other fault contributed to Plaintiffs' alleged injuries and damages.

**THIRTY-THIRD DEFENSE**

690. Should AbbVie be held liable to Plaintiffs, which is specifically denied, AbbVie would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasors for the same injuries alleged in Plaintiffs' Complaint.

**THIRTY-FOURTH DEFENSE**

691. Plaintiffs' claims may be barred because AbbVie at all times conformed to the requirements of the FDA, as well as all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s).

**THIRTY-FIFTH DEFENSE**

692. Plaintiffs' claims may be barred because Plaintiffs have failed to comply with conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

**THIRTY-SIXTH DEFENSE**

693. AbbVie incorporates all available state-law defenses including all defenses applicable under state product liability, consumer protection, unfair competition and/or consumer fraud statutes, whether or not specifically enumerated in the Master Complaint.

**THIRTY-SEVENTH DEFENSE**

694. AbbVie hereby preserves any and all defenses of lack of personal jurisdiction which may be determined to apply in the context of one or more individual complaints.

**THIRTY-EIGHTH DEFENSE**

695. Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs lack standing to bring such claims.

**DEMAND FOR JURY TRIAL**

AbbVie demands a trial by jury.

**WHEREFORE**, AbbVie requests that Plaintiffs' Master Complaint be dismissed in its entirety with prejudice, that judgment be entered in favor of AbbVie, that AbbVie be awarded costs and, to the extent provided by law, attorneys' fees, and any such other relief as the Court may deem proper.

Respectfully submitted,

Dated: May 1, 2015

/s/ David M. Bernick  
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**CERTIFICATE OF SERVICE**

I, Christopher R. Boisvert, hereby certify that on May 1, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Christopher R. Boisvert